CLAIMS

WE CLAIM:

1. A controlled release therapeutic composition comprising a low solubility therapeutic agent, a structural polymer carrier and a solubilizing surfactant.
2. A controlled release therapeutic composition comprising a low solubility therapeutic agent, a structural polymer carrier and a solubilizing surfactant adapted to release a high dose of the therapeutic agent.
3. The composition of Claim 2 wherein the high dose of therapeutic agent is between about 1 μg and 750 mg of the therapeutic agent.
4. The composition of Claim 2 wherein the high dose of therapeutic agent is between about 10 mg and about 250 mg of the therapeutic agent.
5. The composition of Claim 2 wherein the high dose of therapeutic agent is between about 25 mg and about 400 mg of the therapeutic agent.
6. The composition of Claim 2 wherein the therapeutic agent has solubility that is between about 1 μg/ml and about 100 mg/ml.
7. The composition of Claim 2 wherein the therapeutic agent has solubility that is between about 1 μg/ml and about 50 mg/ml.
8. The composition of Claim 2 wherein the amount of structural polymer is between about 1% and 80% by weight of the composition.
9. The composition of Claim 2 wherein the amount of structural polymer is between about 5% and 50% by weight of the composition.
10. The composition of Claim 2 wherein the amount of structural polymer is between about 5% and 15% by weight of the composition.
11. The composition of Claim 2 wherein the structural polymer is polyethylene oxide of about 100,000 to 200,000 molecular weight.
12. The composition of Claim 2 wherein the solubilizing surfactant is selected from the group consisting of polyoxyl 40 stearate, polyoxyl 50 stearate, poloxamers, and a:b:a triblock copolymers of ethylene oxide:propylene oxide:ethylene oxide.

13. The composition of Claim 2 wherein the amount of solubilizing surfactant is between about 5% and 50% by weight of the composition.

14. The composition of Claim 2 wherein the amount of solubilizing surfactant is between about 5% and 40% by weight of the composition.

15. A composition comprising a low solubility therapeutic agent, a structural polymer and a solubilizing surfactant adapted to release the therapeutic agent over a prolonged period of time.

16. A composition comprising a low solubility therapeutic agent, a structural polymer and a solubilizing surfactant wherein the composition is a solid.

17. A controlled release pharmaceutical composition comprising a low solubility therapeutic agent, a structural polymer and a solubilizing surfactant adapted to increase the solubility of the therapeutic agent.

18. A dosage form for controlled release of a therapeutic composition comprising a low solubility therapeutic agent, a structural polymer and a solubilizing surfactant.

19. The dosage form of Claim 18 wherein the dosage form is a matrix system.

20. The dosage form of Claim 18 wherein the dosage form is an osmotic system.

21. The dosage form of Claim 18 wherein the dosage form is adapted to be administered once a day.

22. The dosage form of Claim 18, which is adapted to release a high dose of the therapeutic agent.

23. The dosage form of Claim 22 wherein the high dose of the therapeutic agent is between about 20% and about 90% by weight of the therapeutic composition.

24. The dosage form of Claim 22 wherein the high dose of the therapeutic agent is between about 30% and about 40% by weight of the therapeutic composition.

25. A controlled release oral dosage form for once-a-day administration of a therapeutic agent comprising:

a. A core which comprises:

i. a low solubility therapeutic agent;
ii. a structural polymer;
iii. a solubilizing surfactant;

b. a semipermeable membrane surrounding the core; and

c. an exit orifice through the semipermeable membrane which communicates with the core so as to allow release of the therapeutic agent to the environment;

wherein the dosage form releases the therapeutic agent over a prolonged period of time.

26. The controlled release oral dosage form of Claim 25 adapted to release the therapeutic agent at a substantially zero order release rate.

27. The controlled release oral dosage form of Claim 25 adapted to release the therapeutic agent at a substantially ascending release rate.

28. A method for delivering high doses of low solubility therapeutic agents comprising orally administering the dosage form of Claim 25 to a subject.

29. A method for enhancing the bioavailability of a therapeutic agent comprising orally administering the dosage form of Claim 25 to a subject.